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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,137	NGYUYEN MAI	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,7 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-4, 6-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 5/24/2004, in which several claims were cancelled (claims 2, 4, 8-10, 12-54) and in which several claims were amended (claims 1, 3, 6 and 11). Claims 1, 3-4, 6-7 and 11 are pending in the instant application.

Any rejection of record not addressed herein is withdrawn. This action is FINAL.

Claim Objections

Claim 4 is objected to because of the following informalities: the claim is inconsistent with claim 1 in its referral to the nucleic acid of claim 1. The claim language would be clearer if the word "isolated" was inserted between "The" and "nucleic acid", and if the word "acid" were inserted following the word "nucleic" and before "is". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6-7 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action mailed 11/20/2003 and which are repeated below.**

Each of the claims is directed to an isolated nucleic acid selected from the group consisting of: (i) a nucleic acid that specifically hybridizes to a human EG-1 cDNA (coding region of SEQ ID NO: 1) under stringent conditions, (ii) a nucleic acid encodes a human EG-1 polypeptide (SEQ ID NO: 2), (iii) a nucleic acid that has the same sequence as a nucleic acid amplified from an endothelial cell mRNA template using specific primers, (iv) a DNA encoding an mRNA that can be reverse transcribed to produce a human EG-1 cDNA. Each of these members of the Markush group of claim 1 read on genomic DNAs encoding a human EG-1 polypeptide. The instant specification indicates that the genomic sequences for the human EG-1 gene are known in that it describes in general terms the presence of exons and introns. The genomic sequences associated with the EG-1 gene (e.g. promoter, terminator and intervening sequences) are not in fact described in the specification. There is no basis for the skilled artisan to envision those genomic embodiments encompassed by the rejected claims. Therefore, the skilled artisan would have recognized applicant was not in possession of the claimed invention.

Response to Arguments

Applicant's arguments filed the response of 5/24/2004 have been fully considered but they are not persuasive. The response essentially argues: 1) the amended claims overcome the rejection, 2) there is simply no question that applicants were in possession of a nucleic acid that encodes SEQ ID NO: 2.

Applicants have in fact described a cDNA encoding SEQ ID NO: 2. However, the amended claims still encompass genomic embodiments comprising non-transcribed

sequences. There was simply no basis for the skilled artisan to be able to reliably envision these genomic embodiments based upon the single cDNA sequence disclosed by the instant specification. Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the claimed genus of nucleic acids encoding SEQ ID NO: 2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1, 3-4, 6-7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections necessitated by applicants' amendment of the claims in the response filed 5/24/2004.**

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "polypeptide having the sequence of SEQ ID NO: 2" are unclear. It is unclear whether the term "having" is open (i.e. consisting of) or closed (i.e. comprising) claim language. It would be remedial to amend the claim language to clearly delineate between the two possibilities.

Claim 4 is vague and indefinite in that the metes and bounds of the phrase "has the nucleotide sequence of SEQ ID NO: 1" are unclear. It is unclear whether the term "has" is open (i.e. consisting of) or closed (i.e. comprising) claim language. It would be remedial to amend the claim language to clearly delineate between the two possibilities.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitt et al (WO 99/47655 A; see the entire document) or Schmitt et al (WO 99/53040 A; see the entire document). **This rejection is maintained for reasons of record in the previous office action, mailed 5/24/2004 and which are repeated below.**

Each of the Schmitt et al applications describes human mRNAs, cDNAs and genomic sequences that are obtained from or present in ovarian tumor tissue or normal breast tissue. Specifically, each of the applications teach nucleic acid sequences that encode a protein comprising a polypeptide sequence having 100% identity with SEQ ID NO: 2 (e.g. SEQ ID NO: 259 from WO 99/53040; SEQ ID NO: 65 from WO 99/47655; see the attached sequence search results for 10-029-137-2.rge). The nucleic acid sequences taught in these applications have extensive homology with SEQ ID NO: 1. For example, SEQ ID NO: 65 of WO 99/47655 has 82% similarity to SEQ ID NO: 1, with 99.9% identity across nucleotides 1-1056 of SEQ ID NO:1 (see the attached reports for 10-029-137-1.rge). SEQ ID NO: 259 from application WO 99/53040 has 82% similarity to SEQ ID NO: 1, with 99.9% identity across nucleotides 1-1056 of SEQ ID NO:1 (see the attached reports for 10-029-137-1.rge). Thus, the Schmitt et al applications teach each of the limitations for claim 1, parts (i-v).

Response to Arguments

Applicant's arguments filed the response of 5/24/2004 have been fully considered but they are not persuasive. The response essentially argues: 1) the amended claim is directed to a nucleic acid that is the minimum length to encode SEQ ID NO: 2, and 2) the cited art fails to identify the presently claimed sequence.

Applicant's response appears to be arguing a limitation in the claim that is not actually present. There is no limitation in the amended claims that the nucleic acid is of any particular length. For example, a genomic DNA fragment encoding SEQ ID NO: 2 would still satisfy the limitation of "consisting of" a DNA that encodes SEQ ID NO: 2. Further, it appears the term "having" is intended to be open claim language and, thus, the claims encompass embodiments where the nucleic acid is longer than 534 nucleotides because it encodes a polypeptide comprising SEQ ID NO: 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over (WO 99/47655 A; see the entire document) or Schmitt et al (WO 99/53040 A; see the entire document).

The teachings of the Schmitt et al applications are described above, and applied as before, except:

Schmitt et al do not appear to explicitly teach the use of a labeled nucleic acid encompassed by claim 1.

It would have been prima facie obvious to one of ordinary skill in the art to use a labeled probed corresponding the EG-1 nucleic acids described by Schmitt et al (i.e. SEQ ID NO: 259 from WO 99/53040; SEQ ID NO: 65 from WO 99/47655) to clone the cDNA or genomic DNA sequences from libraries comprising cDNA and/or gDNAs. Alternatively, it would have been obvious to use such labeled probes to identify homologs of the genes identified by Schmitt et al. One would have been motivated to do so in order to clone and express the polypeptides identified by Schmitt et al as being expressed in breast and/or ovarian tumor tissue, or genes encoding homologs thereof. Absent any evidence to the contrary, there would have been a reasonable expectation of success labeling and using nucleic acid probes derived from the nucleic acid sequences taught by Schmitt et al and which are embraced by the rejected claims.

Response to Arguments

Applicant's arguments filed the response of 5/24/2004 have been fully considered but they are not persuasive. The response essentially argues: 1) the nucleic acids taught in the cited prior art are expressed sequence tags, 2) the possible reading frames associated with each tag are not disclosed, and 3) therefore there is no motivation for the skilled artisan to label the DNAs taught in the prior art applications in order to identify a polypeptide whose sequence is not actually disclosed in the prior art applications.

While it is conceded that the prior art application does not specifically disclose the polypeptide comprising SEQ ID NO: 2, or even the particular ORF encoding the protein, it still would have been prima facie obvious to the skilled artisan to label the

nucleic acids taught in the applications in order to identify nucleic acids encoding particular proteins. The abstract of each of the applications teach that the nucleic acids identified (mRNA, cDNA, genomic sequences) therein are obtained from human breast and/or ovarian tissue and that the invention is directed to the polypeptides encoded by the obtained nucleic acid sequences. One would have been motivated to use any of the identified DNAs as probes in order to, for example, identify gDNA clones comprising the genomic DNA encoding the particular EST. In addition, or alternatively, one would have been motivated to use the labeled probe to study expression of the same sequences in other tissues. In either case, one would not necessarily have needed to know the polypeptide sequence encoded by the EST in order to use its labeled probe. Further, the labeled probe could be used to identify clones within an expression library that bind to the particular EST sequence and which may comprise the complete ORF. One then could then identify and obtain the polypeptide encoded by the cDNA clone corresponding to the particular EST. Each of these uses for labeled ESTs are and were known in the art and do not necessarily require prior knowledge of the ORF for their practice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

ggl

GERRY LEFFERS
PRIMARY EXAMINER